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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,272	01/22/2001	Gil H. Choi	PB340P2C2	9690
22195	7590	01/26/2004		
HUMAN GENOME SCIENCES INC 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850				
			EXAMINER DUFFY, PATRICIA ANN	
			ART UNIT 1645	PAPER NUMBER 16

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,272

Applicant(s)

CHOI ET AL.

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 22-32, 34-47, 49-72 and 74-85 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 74-78 is/are allowed.
- 6) ☒ Claim(s) 22-32, 34-47, 49-72 and 79-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 18, 19, 22-32, 34-47, 49-72 and 74-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO AMENDMENT

The amendment filed 8-6-03 has been entered into the record. Claims 18, 19, 22-23, 34-47, 49-60, 62-72 and 74-85 are pending all other claims have been cancelled. Claims 22-23, 34-47, 49-60, 62-72 and 74-85 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 18 and 19 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. At this time claim 62 has not been rendered allowable and as such rejoinder of claim 18 in view of *In re Ochiai*, 71 F3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F3d. 422, 37 USPQ 2d 1663 (Fed. Cir. 1996) is not appropriate at this time. Applicants are reminded that for rejoinder, the rejoined claim must depend or include all limitations from an allowable claim. Additionally, claim 19 is not drawn to a method of use of any claimed polynucleotide and therefore will not be rejoined at any point because it does not include all the limitations of any of the polynucleotide claims.

Rejections Withdrawn

The objection to the title of the invention as not descriptive is withdrawn in view of the amendment.

The rejection of claims 65, 66, 68, 69, 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn based on Applicants' amendments to the claims.

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The rejection of claims 41 and 86-92 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of Applicants' amendments to the claims.

Rejections Maintained

The rejection of claims 22-32, 34-47, 49-60, 62-72 and 79-85 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record in Paper No. 13, mailed 5-6-03.

Applicants argue that the amendment of the claims to recite "consisting of" obviates this issue. This is not persuasive and does not address the issue of variants, hybridizing variants etc. Applicants have not provided written description of variants. Applicants have provided but a single nucleic acid (SEQ ID NO:65), presumably encoding a polypeptide (SEQ ID NO:66). As such, there is no showing of possession of the claimed genus of variants. As set forth previously, the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column). In the instant case, there is no reduction to practice of a representative number of species, no disclosure of relevant identifying

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characteristics or functional characteristics coupled with a known or disclosed correlation between function and structure. The claims as amended still do not meet the written description guidelines. There is no established correlation between structure and function. The function of the SP042 polypeptide encoding by the polynucleotide is not discussed nor disclosed by the specification. Clearly, one skilled in the art would recognized that in the absence of a correlation of structure and function, the disclosure of a single nucleic acid does not describe a genus.

The rejection of claims 22-32, 34-47, 49-60, 62-72 and 79-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide consisting of SEQ ID NO: 65, specific fragments thereof, vectors and host cells consisting of these, it does not reasonably provide enablement for an isolated polynucleotide comprising SEQ ID NO: 65 or a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:66 or epitope bearing portions thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is maintained for reasons made of record in Paper No. 13, mailed 5-6-03.

Applicants arguments have been carefully considered but are not persuasive. Applicants argue that the claims as amendment do not describe any undescribed sequences. This is not persuasive, there are no variants of the nucleic acid sequence or of the polypeptide sequence disclosed. There is no known or disclosed correlation between structure of the nucleic acid and function of the polypeptide. As such, the examiner maintains that the claims encompass undisclosed and undescribed sequences. Applicants argue that the polynucleotides can be used for the detection of Streptococci and as antigens for vaccines. This is not persuasive, the claims are not limited to those that provide for the detection of Streptococci and Applicants have not provided any description of variants of the sequence which could be used as such. While a particular

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described nucleic acid sequence would be expected to hybridize to its homolog, nucleic acid sequences that differ in every third nucleotide (i.e. the encoding language of the claims) would not be expected to hybridize, because it is well established in the hybridization art that at least 15-20 identical consecutive nucleotides are required to form a stable hybrid. When every third nucleotide residue is a wobble position, one would not expect that this nucleic acid would hybridize as asserted. As to vaccines, the specification is devoid of any data indicating that an immune response is naturally generated to the polypeptide encoded by the polynucleic acid. Further, there is not a single piece of evidence that the immune response to such a polypeptide is protective. Protection is required by a vaccine. As such, polynucleic acids encoding polypeptides are not enabled. Applicants admit that they did not disclose the complete ORF and indicate that a more complete listing of the genome can be found in copending application 60/029,960. This does not address the issue. There is no evidence that Applicants were in possession of a polypeptide that is actually expressed by *Streptococcus pneumoniae*. Applicants argue that the polynucleotides have been modified for use as antigens. This again is not persuasive, there is no evidence that the polypeptide sequence is in fact an antigen from *Streptococcus pneumoniae*. Applicants indicate that the complete ORF is disclosed in Table 2 of Serial number 60/029,960. It is noted that this specification must meet the criteria, Applicants can not rely upon essential material in a prior application that is improperly incorporated by reference. Applicants have not provided a comparison of the two sequence in such a manner that unequivocally demonstrates possession of the open reading frame. Further, this argument does not provide evidence for the genus of nucleotides and polypeptides. Applicants are not enabled for their entire scope for reasons supra and already made of record.

The rejection of claim 62 under 35 U.S.C. 102(b) as being anticipated by Birkett et al (U.S. Patent Number 5,302,527) or Boehringer Mannheim 1991 Catalog or Stratagene

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1991 Product Catalog is maintained for reasons made of record in Paper No. 13, mailed 5-6-03.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the claims as amended exclude the prior art in view of the hybridizing to the "full length". This is not persuasive, the prior art would in fact hybridize to the full length. What applicants appear to intend is to require is that the nucleic acid hybridize across the full length of (a) or (b), however, the claims are not so limited.

The rejection of claims 34, 49, 62, 65, 66, 67, 68, 69, 70 and 71 under 35 U.S.C. 102(e) as being anticipated by Bergeron et al (U.S. Patent No. 6,001,564 issued December 14, 1999, filed September 11, 1995) is maintained for reasons made of record in Paper No. 13, mailed 5-6-03.

Applicants argue that Bergeron et al does not teach an open reading frame or contemplate any epitopes. This is not persuasive, the nucleic acid of the prior art has in common structure with SEQ ID NO:65 as set forth in the last office action of record. The disclosure of the nucleic acid anticipates the instantly claimed invention in view of the alignments provided. To reiterate the double stranded nucleic acid of the prior art encodes a protein having 29 consecutive amino acids in common with SEQ ID NO:66 (see attached alignment). Recognition of an open reading frame is not required by the prior art, merely that the nucleic acid structure meet the limitations of the claims. The examiner has provided an alignment that the nucleic acid structure would encode 29 consecutive amino acids in common with SEQ ID NO:66 and as such anticipates the claims. The claims are drawn to a nucleic acid and the nucleic acid structure inherently meets the encoding language of the claims. The rejection is maintained across claim 62. Applicants argue that the claim 62 as amended exclude the prior art in view of the hybridizing to the "full length". This is not persuasive, the prior art would in fact hybridize to the full

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length. What applicants appear to intend is to require is that the nucleic acid hybridize across the full length of (a) or (b), however, the claims are not so limited.

Status of Claims

Claims 18, 19 are withdrawn from consideration. Claims 22-23, 34-47, 49-60, 62-72 and 79-85 stand rejected. Claims 74-78 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555 or 571-272-0855 after January 27, 2004. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patricia A. Duffy
Patricia A. Duffy

Primary Examiner

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